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Attorney Docket No.: 14230-0010002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Frederick L. Hall et al. Art Unit : 1647
Patent No. : 7,459,541 Examiner : Regina M. Deberry
Issue Date : December 2, 2008 Conf. No. : 4628
Serial No. : 10/733,852
Filed : December 10, 2003
Title : MATRIX-TARGETED FUSION POLYPEPTIDES FOR TISSUE
 REGENERATION AND WOUND HEALING

Commissioner for Patents
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RESPONSE TO DECISION ON REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT

In a Decision on Request for Reconsideration of Patent Term Adjustment ("Decision") dated July 17, 2009, the United States Patent and Trademark Office ("Office") partially granted Patentee's Application For Patent Term Adjustment (PTA) Under 37 C.F.R. § 1.705(d) for the above patent. The Office agreed with Patentee's request that the patent be accorded 723 days of "B Delay;" however, the Office did not follow Patentee's request to apply the rule set forth in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008) with respect to the calculation of "overlap" of "A Delay" and "B Delay." The legal issue concerning the calculation of such "overlap" is identical to the legal issue decided by *Wyeth*. Following the *Wyeth* precedent would result in a total PTA calculation of 907 days, for the reasons detailed in Patentee's Application for PTA filed on January 29, 2009.

The Office acknowledged that Patentee requested recalculation of PTA according to the rule set forth in *Wyeth*. Decision at page 1. However, that acknowledgement was the sole mention of the *Wyeth* case in the entire Decision. Most of the Decision puts forth the Office's support for a legal argument that had been considered and rejected by the court in *Wyeth*. The Office's arguments appear to be presented anew in the Decision as though the *Wyeth* case has no relevance to the present PTA calculation.

The statute governing PTA instructs a patentee dissatisfied with a determination made by the Director to pursue a civil action against the Director in the United States District Court for the District of Columbia. 35 USC §154(b)(4)(A). The statute makes clear that the District Court for the District of Columbia is the sole court with jurisdiction to hear such PTA challenges.

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It was under this statutory provision that Wyeth brought its action against the Director and prevailed on the exact same legal issue that is in contention for the present patent. Still, and despite the previous adverse ruling on this legal issue, the Office in the present Decision has ignored the clear ruling of the only district court with authority to consider PTA challenges.

As the identical legal issue of the present PTA challenge has already been decided by the only district court with authority to consider PTA challenges, Patentee submits that the Office should either follow the law as interpreted by that court or stay a final decision in this matter until the ongoing appeal of the *Wyeth* decision has been decided by an appellate court.

Subsequent to the *Wyeth* decision, numerous patentees have filed suits in the District Court for the District of Columbia challenging PTA calculations based on the same legal issue presented in *Wyeth*. Because the District Court for the District of Columbia has already decided the issue and the Office has appealed that decision to the Federal Circuit, the Office and the plaintiffs have requested stays of most or all of those litigations pending the outcome of that appeal. Fairness dictates that the Office act in a consistent manner during the present administrative process. Given its current legal posture, it would be fundamentally unfair for the Office to render a final ruling on this issue when its interpretation of the statute and rules have been rejected by the court and it is currently seeking to have that adverse ruling reversed on appeal.

The Decision states that "Patentee's calculation of the period of overlap is inconsistent with the Office's interpretation of this provision [of 35 USC §154(b)(2)(A)]." Decision at page 2. However, as noted above, the district court with sole jurisdiction to hear PTA challenges has squarely rejected the Office's interpretation of this statutory provision. "While deference is to be given to an agency's interpretation of the statute it administers [citations omitted], it is the courts that have the final word on matters of statutory interpretation." *Ithaca College v. NLRB*, 623 F.2d 224, 228 (2d Cir. 1980) (citing *inter alia Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177, 2 L.Ed. 60 (1803)). By comparison to the Office's apparent disregard for the precedent of the District Court for the District of Columbia in calculating PTA for the present patent, the National Labor Relations Board has been admonished for its practice of refusing to follow unfavorable decisions from the courts in instances where it was likely that a case at issue would come up for review before the very court with which the Board disagrees.

Of course, we do not expect the Board or any other litigant to rejoice in all the opinions of this Court. When it disagrees in a particular case, it should seek review in the Supreme Court. During the interim before it has sought review or while review is still pending, it would be reasonable for the Board to stay its proceedings in another case that arguably falls within the precedent of the first one. However, the Board cannot, as it did here, choose to ignore the decision as if it had no force or effect. Absent reversal, that decision is the law which the Board must follow. The Board cites no contrary authority except its own consistent practice of refusing to follow the law of the circuit unless it coincides with the Board's views. This is intolerable if the rule of law is to prevail.

Id. Similarly, absent a reversal by the Federal Circuit or the Supreme Court, the Office cannot act in a manner that ignores the *Wyeth* decision as if it had no force or effect.

Patentee requests that the court follow the legal authority of *Wyeth* and increase total PTA for the present patent to 907 days (for the same reasons detailed in the Application for PTA filed on January 29, 2009). If the Office is unwilling to follow the ruling in *Wyeth* while the appeal of that decision is ongoing, then it should at a minimum follow the rationale it has put forth recently in PTA litigations pending before the District Court for the District of Columbia and stay a final decision on this matter until the *Wyeth* appeal has been completed. It is the courts, and not the Office, that must have the final word on this matter of statutory interpretation.

No fee is believe due. However, if any fee is due, please charge it to Deposit Account No. 06-1050, referencing Attorney Docket Number 14230-0010002.

Respectfully submitted,

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